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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,528	07/07/2005	Thomas Julius Borody	119381-00003 / 3704US	1484

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K&L Gates LLP
3580 Carmel Mountain Road
Suite 200
San Diego, CA 92130

EXAMINER	
HOBBS, LISA JOE	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,528	BORODY, THOMAS JULIUS	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-17,19-29 and 31-37* is/are pending in the application.

4a) Of the above claim(s) *19-29 and 31-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11 and 13-17, drawn to a biphasic culture medium and a kit comprising same.

Group II, 19-29 and 31-37, drawn to a method of detecting protozoa.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The biphasic culture medium that is common to each of the individual inventions in groups I-II was well-known in the art at the time the claimed invention was made, and therefore, the inventions of groups I-II lack the same special technical feature (see, for example, Clark et al., Clin Microbiol Reviews July 2002).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet al.l criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement set forth in the action of 20 September 2007 is withdrawn in view of the petition for review of 20 June 2008 and petition decision of 26 August 2008. The current restriction was set forth in a dedicated communication and, as the two month deadline for requesting reconsideration has passed, the requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al.. ((2002) Clin. Microbiol. Rev. 15(3): 329-341) and Nakamura ((1953) Bacteriol. Rev.

17(3): 189-212), in view of Shimakita et al. (US 2003/0003527 A1) and Petri et al. (US 5272058 A).

A bi-phasic culture medium is claimed, along with a kit comprising the medium.

Clark et al. beneficially teach LE medium, a diphasic medium, which is a modification of Boeck and Drbohlav's medium. Clark et al. teach that Locke's solution is prepared by dissolving in 1 liter, sodium chloride, calcium chloride, potassium chloride, magnesium chloride, sodium phosphate, sodium bicarbonate, and potassium phosphate. Clark et al. further beneficially teach that egg slants are prepared as the solid phase of the LE medium (see, for example, page 332, column 2). Furthermore, Clark et al. teach that human or horse serum has been used in the Locke's solution liquid phase of LE medium of prior art versions of the medium (see, for example, page 334, column 2).

Clark et al. does not expressly teach a medium wherein the liquid phase contains peptone and optionally an antibiotic.

Nakamura beneficially teach that Boeck and Drbohlav's medium, Locke-egg-serum medium (LES medium) was the first successful cultivation of *E. histolytica* and since then, many modifications to their medium have been made. Nakamura beneficially teach that peptones as well as antibiotics, such as penicillin, have been used in the culture media of amoeba, as growth factors, and as means for eliminating bacteria from the cultures (see, for example, page 195 and 202). Furthermore, Nakamura beneficially teach that although an optimal salt concentration is 0.94%, *E. histolytica* can tolerate considerable changes in tonicity, and that phosphate buffer is essential (see, for example, page 200). Furthermore, Nakamura beneficially teach that according

to Boeck and Drbohlav, amoeba's grew best in cultures having an initial pH of 7.2 to 7.8 (see, for example, page 198).

Shimakita et al. and Petri et al. teach kits comprising media for bacterial growth. Petri et al. specifically teach kits for the detection of E. hystolitica. Shimakita et al. teach "[t]he microorganism detecting kit has a feature that the specimen contact means contains a culture medium for culturing microorganisms. Thus, in the microorganism detecting kit according to the present invention, it is possible to prevent a reduction in activity of microorganisms deposited on the specimen contact means after contact of the compound(s) with the specimen" [0088].

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the medium disclosed by Clark et al., with respect to adding peptones and antibiotics, based upon the beneficial teachings provided by Nakamura with respect to the art-recognized benefits of adding peptones and antibiotics to culture mediums, as discussed above. Clark et al. beneficially teach a bi-phasic medium which provides an egg slant and a liquid phase which has phosphate-buffered saline and serum. Furthermore, Nakamura beneficially teach that the LES medium described by Clark et al. has had many modifications, among which have been the addition of peptones as growth factors and antibiotics as means to eliminate unwanted bacteria from the culture. The result-effective adjustment of particular conventional working conditions (e.g., providing particular concentrations of ingredients within the medium, providing particular ingredients, such as particular antibiotics or peptones) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, as discussed by Nakamura above. Shimakita et al. and Petri et al.

teach that kits for the detection of bacteria in any configuration desired by the user are well within the knowledge of one of skill in this art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh